

Special 510(k) Premarket Notification GE Medical Systems - Vivid 7 with TSI May 27, 2003

# JUN - 9 2003

# Attachment B:

Summary of Safety and Effectiveness Prepared in accordance with 21 CFR Part 807.92(c).



GE Medical Systems

General Electric Company P.O. Box 414. Milwaukee, WI 53201

#### Section a):

1.

Submitter: GE Medical Systems

PO Box 414

Milwaukee, WI 53201

Allen Schuh. Contact Person:

Manager, Safety and Regulatory Engineering

Telephone: 414-647-4385; Fax: 414-647-4090

May 27, 2003 Date Prepared:

2. Device Name:

GE Vivid 7 Diagnostic Ultrasound System with TSI

Ultrasonic Pulsed Echo Imaging System, 21 CFR 892.1560, 90-IYO Ultrasonic Pulsed Doppler Imaging System, 21 CFR 892.1550, 90-IYN

Marketed Device: GE Vivid 7 Diagnostic Ultrasound System K003931 (90-IYO/IYN)

A device currently in commercial distribution.

- 4. Device Description: The GE Vivid 7 Diagnostic Ultrasound is a full featured echocardiography imaging and analysis system. It consists of a mobile console approximately 65 cm wide, 96 cm deep and 139 cm high that provides digital acquisition, processing and display capability. The user interface includes a computer keyboard, specialized controls and a color video CRT display. This modification will provide users with enhanced ability to evaluate wall motion during echocardiography.
- 5. Indications for Use: The device is intended for use by a qualified physician for ultrasound evaluation of Fetal; Abdominal (including renal and GYN); Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular (PV); Musculo-skeletal Conventional; Urology (including prostate), Transesophageal; Transrectal (TR); Transvaginal (TV); and Intraoperative (abdominal, thoracic, & vascular).
- 6. Comparison with Predicate Device: The GE Vivid 7 with TSI is of a comparable type and substantially equivalent to the current GE Vivid 7. It has the same technological characteristics, key safety and effectiveness features, physical design, construction, and materials, and has the same intended uses and basic operating modes as the predicate device.

#### Section b):

- 1. Non-clinical Tests: The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness, electromagnetic compatibility, as well as thermal, electrical and mechanical safety, and has been found to conform with applicable medical device safety standards.
- 2. Clinical Tests: None required.
- 3. Conclusion: Intended uses and other key features are consistent with traditional clinical practice, FDA guidelines, and established methods of patient examination. The design and development process of the manufacturer conforms with 21 CFR 820, ISO 9001:2000 and ISO 13485 quality systems. The device conforms to applicable medical device safety standards and compliance is verified through independent evaluation with ongoing factory surveillance. Diagnostic ultrasound has accumulated a long history of safe and effective performance. Therefore, it is the opinion of GE Medical Systems that the GE Vivid 7 Diagnostic Ultrasound with TSI is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.



JUN - 9 2003

Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

Mr. Allen Schuh Manager, GE Ultrasound Safety and Regulatory Engineering GE Medical Systems P.O. Box 414 MILWAUKEE WI 53201

Re: K031663

Trade Name: GE Vivid 7 with TSI Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulation Number: 21 CFR 892.1560

Regulation Name: Ultrasound pulsed echo imaging system

Regulation Number: 21 CFR 892.1570

Regulation Name: Diagnostic ultrasonic transducer

Regulatory Class: II

Product Code: 90 IYN, IYO, and ITX

Dated: May 27, 2003 Received: May 29, 2003

#### Dear Mr. Schuh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the GE Vivid 7 with TSI, as described in your premarket notification:

### Transducer Model Number

3.5C

<u>5C</u>

M7C 7L 10L 12L M<sub>12</sub>L <u>3S</u> <u>5S</u> <u>7S</u> **10S** M3S E8C 6T <u>7T</u> <u>8T</u> 9T P2D P<sub>6</sub>D i8L i13L

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration Center for Devices and Radiological Health Document Mail Center (HFZ-401) 9200 Corporate Boulevard Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801, please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Carolyn Y. Neuland For Nancy C. Brogdon

Director, Division of Reproductive, Abdominal and Radiological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure(s)

### **GE Vivid 7 Ultrasound System**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	=	Mode of Operation									
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler		Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic						_					
Fetal / Obstetrics	Р	P	Р	Р	Р	P	_ P	Р	Р		
Abdominal <sup>[1]</sup>	Р	Р	P	Р	Р	Р	P	Р.	P		
Pediatric	Р	Р	Р	Р	Р	Р	Р	P	Р		
Small Organ <sup>[2]</sup>	Р	P	Р		Р	P	P	Р			
Neonatal Cephalic	Р	Р	Р	Р	Р	Р	Р	Р	P		
Adult Cephalic	Р	Р	P	Р	P	Р	Р	Р	P		
Cardiac <sup>[3]</sup>	P	Р	P	Р	Р	Р	Р	Р	P		
Peripheral Vascular	Р	P	Р	Р	Р	Р	Р	P			
Musculo-skeletal Conventional	Р	Р	P		Р	Р	Р	Р			
Musculo-skeletal Superficial											
Other <sup>[4]</sup>	Р	P	P_	Р	Р	Р	Р	Р	Р		
Exam Type, Means of Access											
Transesophageal	Р	P	Р	Р	Р	Р	P	Р	Р		
Transrectal	P	P	P		Р	P	Р	Р			
Transvaginal	Р	Р	Р		Р	Р	Р	Р			
Transuretheral											
Intraoperative <sup>[5]</sup>	Р	Р	Р	Р	Р	Р	Ρ	Р	Р		
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic

- [2] Small organ includes breast, testes, thyroid.
- [3] Cardiac is Adult and Pediatric.
- [4] Other use includes Urology/Prostate
- [5] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
- [\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number\_

# GE Vivid 7 with 3.5C Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	<del></del>	Mode of Operation									
Clinical Application Anatomy/Region of Interest	В	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power	Combined	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics	Р	P	P		Р	Р	P	P	P	Р	
Abdominal <sup>(1)</sup>	Р	Р	P		Р	Р	Р	Р	Р	Р	
Pediatric	Р	P	P		Р	Р	Р	P	P	P	
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											<b>_</b>
Cardiac				ļ							
Peripheral Vascular											ļ
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											ļ
Other <sup>[4]</sup>	Р	Р	P		Р	Р	Р	Р	Р	Р	
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)			ļ								
Intraoperative Neurological											
Intravascular											
Laparoscopic			h FDA					ليييا		- dez	

	i						 	
N = new indication; P = pr	eviously cleared	by FDA; E	= added und	er Appe	endix E		 	
Notes: [1] Abdominal incl	udes GYN;							
[4] Other use inclu	ıdes Urology;							
[*] Combined mod	les are B/M, B/C	olor M, B/PV	VD, B/Color/f	PWD, B	/Power/F	WD.		
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# GE Vivid 7 with 5C Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation										
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color	Color M	Power	T	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics	Р	Р	Р		P	P	Р	Р		Р	
Abdominal <sup>[1]</sup>	Р	P	Р		Р	Р	Р	P		Р	
Pediatric	Р	Р	P		Р	Р	Р	Р		Р	
Small Organ (specify)					ļ						ļ <u>.</u>
Neonatal Cephalic											
Adult Cephalic											
Cardiac					ļ			· ·			
Peripheral Vascular	Р	Р	Р		Р	Р	Р	Р		Р	
Musculo-skeletal Conventional					ļ						ļ <u> </u>
Musculo-skeletal Superficial											
Other <sup>[4]</sup>											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)					ļ <u></u> -						
Intraoperative Neurological											
Intravascular											
Laparoscopic			b 5DA		<u> </u>					<u> </u>	<u> </u>

v = new indication, P = previously cleared by PDA, E = added didder Appendix E	
Notes: [1] Abdominal includes GYN/Pelvic, Renal and Aorta-iliac artery;	
[*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.	
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# **GE Vivid 7 with 8C Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation										
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color	Color M	Power	Combined	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											<u> </u>
Fetal / Obstetrics											
Abdominal <sup>[1]</sup>	E	E	E		E	E	E	E		E	<u> </u>
Pediatric	Ε	E	E		E	Ε	E	E		E	
Small Organ (specify)	E	E	E		E	Ε	_ E	E		E	
Neonatal Cephalic	Е	E	E		E	E	E	_E_		E	<u> </u>
Adult Cephalic											
Cardiac											
Peripheral Vascular	E	E	E		E	E	E	_E_		_E_	L
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other <sup>[4]</sup>											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular '											
Laparoscopic			<u></u>							<u></u>	<u> </u>

N = new indication; P = previously cleared by FDA; E = added under Append	xit	E
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Notes:	[1] Abdominal includes	GYN/Pelvic,	Renal and	Aorta-iliad	artery;	

[\*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.

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# **GE Vivid 7 with M7C Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation										
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler		Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics	_E_	E	_ E		E	E	E	E		E	
Abdominal <sup>[1]</sup>	E	E	E		E	_ E	Ε	E		E	
Pediatric	E	E	E		_E	Ε	Ε	Ε		E	
Small Organ (specify)	E	E	E		E	E	E	E		E	
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular	E	E	E		E	E	E	E		Ε	
Musculo-skeletal Conventional	-										
Musculo-skeletal Superficial											
Other <sup>[4]</sup>											
Exam Type, Means of Access							<u></u>				
Transesophageal											
Transrectal				. <u>_</u>							
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previous	sly cleared by FDA;	E = added under Appendix 6	Ξ
Notes: [1] Abdominal includes	GYN/Pelvic, Renal a	and Aorta-iliac artery;	

[*] Combined modes are B/I	M, B/Color M, B/PWD, B	//Color/PWD, B/Power/PW	/D.
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# **GE Vivid 7 with 7L Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	<del></del>	Mode of Operation									
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color	Color M	Power	Combined	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics											<u></u>
Abdominal											
Pediatric	Р	Р	P		Р	P	Р	P		Р	
Small Organ <sup>[2]</sup>	Р	Р	Р		Р	Р	Р	Р		Р	
Neonatal Cephalic								<u> </u>			
Adult Cephalic											
Cardiac											
Peripheral Vascular	Р	Р	Р		Р	Р	Р	P_		Р	
Musculo-skeletal Conventional	Р	P	Р		Р	P	Р	Р		Р	
Musculo-skeletal Superficial											
Other <sup>[4]</sup>											
Exam Type, Means of Access											
Transesophageal											
Transrectal							<u></u>				
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E	
Notes: [2] Small organ includes breast, testes, thyroid.	
[*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.	
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510(k) Number <u>K03/663</u>

# **GE Vivid 7 with 10L Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation										
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW	Color Doppler	Color M	Power	Combined	Harmonic Imaging	Coded Pulse	
Ophthalmic							ļ				
Fetal / Obstetrics											
Abdominal											
Pediatric	Р	Р	P		Р	Р	Р	Р		Р	
Small Organ <sup>[2]</sup>	Р	Р	Р		Р	Р	Р	P		þ	
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular	P	Р	Р		Р	Р	Р	P		Р	
Musculo-skeletal Conventional	P	Р	Р	<u>-</u> _	P	Р	Р	P		P	
Musculo-skeletal Superficial							 				
Other (specify)											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative <sup>[5]</sup>	Р	Р	Р		Р		Р	Р			
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously o	leared by FDA;	E = added under	Appendix E
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Notes:	[2] Small organ	includes breast,	testes, thyroid.
110100.	[2] Oman organ	morado broad,	tootoo, any total

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510(k) Number <u>KO3/662</u>

<sup>[5]</sup> Intraoperative includes abdominal, thoracic, and vascular.

<sup>[\*]</sup> Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.

# **GE Vivid 7 with 12L Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation										
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color	Color M Doppler	Power	Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics											
Abdominal							ļ				
Pediatric	Р	Р	P		Р	Р	Р	Р		P	
Small Organ <sup>[2]</sup>	Р	P	P		Р	Р	Р	P		Р	
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular	Р	P	P		Р	Р	P	Р		Р	
Musculo-skeletal Conventional	P	P	P		Р	Р	Р	Р		Р	
Musculo-skeletal Superficial											
Other (specify)											
Exam Type, Means of Access											
Transesophageal											·
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular	·										
Laparoscopic											L

N = new indication; $P = previously cleared by FDA$ ; $E = added under Appendix E$	
Notes: [2] Small organ includes breast, testes, thyroid.	
[*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.	
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# **GE Vivid 7 with M12L Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation										
Clinical Application  Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler		Combined	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric	Ε	_E_	E		E	E	E	E		E	
Small Organ <sup>[2]</sup>	E	E	E		E	E	E	E		E	
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular	Ε	E	E		Е	E	E	E		E	
Musculo-skeletal Conventional	E	Ε	E		E	E	E	Ε		_E	
Musculo-skeletal Superficial											
Other (specify)											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)	E	_ E	E		E	E	Е	E		E	
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E
Notes: [2] Small organ includes breast, testes, thyroid.
[*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.
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510(k) Number <u>X03/663</u>

# GE Vivid 7 with 3S Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

		Mode of Operation									
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW	Color Doppler	Color M Doppler		Combined	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics	Р	Р	Р	Р	Р	Р	Р	P	P		
Abdominal <sup>[1]</sup>	Р	Р	Р	Р	Р	Р	Р	Р	Р		
Pediatric	Р	Р	Р	Р	P	Р	Р	Р	P		
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic	Р	Р	Р	Р	Р	Р	Р	P	Р		
Cardiac <sup>[3]</sup>	Р	Р	Р	Р	Р	Р	Р	Р	P		
Peripheral Vascular										 	
Musculo-skeletal Conventional										. <u> </u>	
Musculo-skeletal Superficial											
Other <sup>[4]</sup>	Р	P	Р	Р	р	Р	Р	Р	Р		L
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic		·									

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Notes:	[1]	Abdominal includes	GYN

- [3] Cardiac is Adult and Pediatric;
- [4] Other use includes Urology;
- [\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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# **GE Vivid 7 with 5S Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation										
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler		Combined	Harmonic Imaging	Coded Pulse	
Ophthalmic				ļ 							
Fetal / Obstetrics	Р	Р	P	Р	Р	Р	Р	Р	P		
Abdominal <sup>[1]</sup>	Р	Р	Р	Р	þ	Р	Р	P	Р		
Pediatric	Р	Р	Р	Р	Р	Р	P	P	P		
Small Organ (specify)											
Neonatal Cephalic			ļ								
Adult Cephalic			ļ								
Cardiac <sup>[3]</sup>	Р	Р	Р	Р	Р	Р	Р	P	Р		ļ
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other <sup>[4]</sup>	P	Р	Р	Р	Р	Р	Р	Р	Р		
Exam Type, Means of Access											
Transesophageal				 							
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N	- new inc	dication: I	P = nrevio	าบรโบก	deare	d by Ff	A· F	= added	Lunder	Annen	dix F	Ξ

Notes:	Abdominal inc	ludes GYN;

- [3] Cardiac is Adult and Pediatric;
- [4] Other use includes Urology;
- [\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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# **GE Vivid 7 with 7S Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation										
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler		Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics	Р	P	Р	P	Р	Ρ.	Р	Р	P		
Abdominal <sup>[1]</sup>	Р	Р	Р	Р	Р	Р	Р	Р	Р		
Pediatric	Р	P	Р	Р	Р	Р	Р	Р	Р		
Small Organ (specify)											
Neonatal Cephalic	Р	Р	Р	Р	Р	Р	P	P	Р		
Adult Cephalic											
Cardiac <sup>[3]</sup>	Р	P	Р	P	Р	Р	Р	Р	P		
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											i 
Other (specify)											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular '											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN;

[3] Cardiac is Adult and Pediatric.

[4] Other use includes Urology and GYN.

[\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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510(k) Number 7.03/60

# **GE Vivid 7 with 10S Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation										
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M	Power		Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics			<u> </u>								ļ
Abdominal			ļ								·
Pediatric	Р	Р	Р	Р	Р	Р	Р	<u>P</u> _	P		
Small Organ (specify)											
Neonatal Cephalic	Р	Р	Р	Р	Р	Р	Р	Р	Р		ļ
Adult Cephalic											
Cardiac <sup>[3]</sup>	Р	Р	Р	Р	Р	Р	Р	P	Р		
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											ļ
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

Laparoscopic	<u> </u>	1	<u>L</u>	l		<u> </u>		l	<u> </u>	<u> </u>	<u> </u>
N = new indication; P = p	reviously	/ cleared	by FDA	E = ac	lded und	ler Appe	ndix E				
Notes: [3] Cardiac is Adu	ılt and P	ediatric.									
[*] Combined mod	des are E	3/M, B/C	olor M, I	3/PWD d	or CWD,	B/Color/	PWD or	CWD, E	3/Power/F	WD.	
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510(k) Number <u>XOS/66'3</u>

# **GE Vivid 7 with M3S\_Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	<del></del>	Mode of Operation									
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M	Power	Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics	Р	Р	P	Р	Р	Р	Р	Р	Р		
Abdominal <sup>[1]</sup>	Р	Р	Р	P	Р	Р	Р	Р	Р		ļ
Pediatric	Р	P	Р	Р	Р	P	Р	Р	P		
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic	Р	P	Р	Р	Р	Р	Р	P	P		
Cardiac <sup>[3]</sup>	Р	Р	Р	Р	Р	Р	Р	P	Þ		
Peripheral Vascular							,				
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)	Р	Р	Р	Р	Р	Р	P	Р	P		
Exam Type, Means of Access					 						
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											-
Intravascular											
Laparoscopic											

N = new indication; P =	previously cleared by FDA;	E = added under	Appendix E
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Notes:	[1]	Abdomin	al in	cludes	Renal	and	GY	V:
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- [3] Cardiac is Adult and Pediatric.
- [4] Other use includes Urology;
- [\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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510(k) Number <u>X03/663</u>

# **GE Vivid 7 with E8C Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation										
Clinical Application Anatomy/ Region of Interest	В	М	PW Doppler	CW Doppler	Color	Color M	Power	Combined	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics	Р	Р	P		Р	Р	Р	P			
Abdominal <sup>[1]</sup>	Р	P	Р		Р	Р	Р	Р		 	
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other <sup>[4]</sup>	Р	Р	Р		Р	Р	Р	P			
Exam Type, Means of Access											
Transesophageal											
Transrectal	Р	Р	Р		Р	Р	P	P			
Transvaginal	Р	Р	P		Р	Р	P	Р			
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N:	= new	indica	tion: P	= previously	/ cleared	d by FDA:	E = a	dded under	Appendi	хE

N	otes:	[1	] A	νpa	lom	inal	incl	ludes	GY	N/F	elvic;	,
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<sup>[4]</sup> Other use includes Urology/Prostate;

<sup>[\*]</sup> Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.

# **GE Vivid 7 with 6T Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

		<del></del>	т	Mode	OI OP					
В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler			Harmonic Imaging	Coded Pulse	_
:		<u></u>								
		<u> </u>	<b></b>							<u> </u>
		<u> </u>								<u> </u>
!										
P	Р	Р	P	Р	Р	Р	P	Р		
										L
										ļ
										<u> </u>
		ļ								
P	P_	P	Р	Р	Р	Р	P	P		
	P	P P	P P P	P P P P	P P P P P P	Doppler Doppler Doppler Doppler  Doppler Doppler Doppler Doppler  Doppler Doppler Doppler	Doppler Doppler Doppler Doppler Doppler Doppler Doppler	Doppler Doppler Doppler Doppler Doppler Modes  Doppler Doppler Doppler Doppler Doppler Modes  Doppler Doppler Doppler Doppler Doppler Modes	Doppler Doppler Doppler Doppler Doppler Modes Imaging  Doppler Doppler Doppler Doppler Doppler Modes Imaging  Doppler Doppler Doppler Doppler Doppler Modes Imaging  Doppler Modes Imaging  Doppler Modes Imaging	Doppler Doppler Doppler Doppler Doppler Modes Imaging Pulse  Doppler Doppler Doppler Doppler Modes Imaging Pulse  Doppler Doppler Doppler Doppler Modes Imaging Pulse  Doppler Modes Imaging P


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# **GE Vivid 7 with 7T Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	<del></del>	~	<u></u>	- 11- 13-	Mode	of Op	eration	 1			
Clinical Application Anatomy/ Region of Interest	В	M	PW Doppler	CW Doppler	Color	Color M	Power		Harmonic Imaging	Coded Pulse	
Ophthalmic					<u> </u>						
Fetal / Obstetrics											
Abdominal											
Pediatric											
Small Organ (specify)											
Neonatal Cephalic			ļ <u></u>								
Adult Cephalic											
Cardiac	Ε	E	E	E	Е	E	E	E	E		
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											
Exam Type, Means of Access		· •									
Transesophageal	E	<u>E</u>	E	E	E	E	E	E	E		ļ <u>.</u>
Transrectal											
Transvaginal											
Transuretheral		***									
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular		·									
Laparoscopic											

otes: [*] Combined r	modes are B/M, B	/Color M, B/PW	D or CWD, B/Co	lor/PWD or CWD	, B/Power/PWD.

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# **GE Vivid 7 with 8T Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

				, <u>"</u>	Mode	of Op	eration	<u> </u>			-
Clinical Application Anatomy/ Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler		Combined	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics											
Abdominal			<u> </u>								
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac <sup>[3]</sup>	Р	Р	P	Р	Р	Р	P	Р	Р		
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											
Exam Type, Means of Access			· .								
Transesophageal	Р	Р	Р	Р	Р	Р	Р	Р	P		
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication	n; P = previously cleared by FDA; E = added under Appendix E
Notes: [3] Cardia	c is Adult and Pediatric;
[*] Combi	ned modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
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	and Radiological Devices
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# **GE Vivid 7 with 9T Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					Mode	of Op	eration	า			
Clinical Application Anatomy/ Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics											
Abdominal			L								
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac	E	_E_	E_	E	Е	E	E	Ε	E		
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											
Exam Type, Means of Access											
Transesophageal	E	E	E	Ε	Е	E	E	E	E		
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular			ı								
Laparoscopic  N = pew indication: P = pre											

lotes: [*] Combined	d modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/F	WD.
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# **GE Vivid 7 with P2D Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	<del></del>		<del></del>		Mode	of Op	eration	 า		6 <del>7 6</del>	
Clinical Application Anatomy/ Region of Interest	В	М	PW Doppler	CW Doppler	Color	Color M	Power	Combined	Harmonic Imaging	Coded Pulse	
Ophthalmic			<u>                                     </u>								ļ
Fetal / Obstetrics			<u> </u>		ļ						Ĺ
Abdominal											ļ
Pediatric			<u> </u>								
Small Organ (specify)			<u> </u>								ļ
Neonatal Cephalic			<u> </u>								
Adult Cephalic											
Cardiac <sup>[3]</sup>			Р	Р							
Peripheral Vascular			P	P							
Musculo-skeletal Conventional											
Musculo-skeletal Superficial			<u> </u>								
Other (specify)											
Exam Type, Means of Access							<u> </u>				
Transesophageal											
Transrectal											
Transvaginal			ļ								
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic  N = new indication: P = nre		-1	Lb. FD4		al a al						

N = new indication; P = previously cleared by FDA; E = added under Appendix E											
Notes: [3] Cardiac is Adult and Pediatric.											
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510(k) Number 703/663

# GE Vivid 7 with P6D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

İ	Mode of Operation										
Clinical Application  Anatomy/ Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler		Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics											
Abdominal				ļ 				i			
Pediatric			<u> </u>	<u> </u>							
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac <sup>[3]</sup>			Р	Р							
Peripheral Vascular			P	Р							
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral					_						
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											
N = new indication; P = pre Notes: [3] Cardiac is Adult	-		by FDA	; E = ad	ded und	er Appe	ndix E				
				-	<del></del> .						
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510(k) Number 502/663

# GE Vivid 7 with i8L Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					Mode	of Op	eration	n			
Clinical Application Anatomy/ Region of Interest	В	М	PW Doppler	CW Doppler	Color	Color M Doppler	Power	Combined	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics											
Abdominal <sup>[1]</sup>	P	Р	Р		Р	Р	Р	P			
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac <sup>[3]</sup>	Р	Р	Р		Р	Р	P	Р			
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative <sup>[5]</sup>	Р	Р	Р		Р _	Р	Р	Р			
Intraoperative Neurological											
Intravascular										ı	
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E							
	Ν	= new indication:	P = previousl	v cleared by	v FDA: E	= added under	Appendix F

Notes:	[1]	Abdominal	is via	Intraoperativ	e:

[3] Cardiac is Adult and Pediatric via Intraoperative;

[5] Intraoperative includes abdominal, thoracic, and vascular.

[\*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.

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# GE Vivid 7 with i13L Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					Mode	of Op	eration	 1			
Clinical Application Anatomy/ Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power	Combined Modes	Harmonic Imaging	Coded Pulse	_
Ophthalmic											
Fetal / Obstetrics											
Abdominal <sup>[1]</sup>	Р	Р	P		Р	Р	Р	Р			
Pediatric											
Small Organ (specify)											
Neonatal Cephalic			<u> </u>								
Adult Cephalic			<u></u>								
Cardiac <sup>[3]</sup>	P	Р	P		Р	Р	Р	P			
Peripheral Vascular											
Musculo-skeletal Conventional			ļ								
Musculo-skeletal Superficial			<u> </u>								
Other (specify)			ļ <u>.</u> -								
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative <sup>[5]</sup>	Р	Р	Р		Р	Р	Р	Р			
Intraoperative Neurological											
Intravascular			,								
Laparoscopic											

	Ν:	= new indication:	:P≈	previously	cleared by	v FDA;	E = a	idded under	Appendix	E
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Notes:	111	Abdo	minal	is via	Intraon	erative:
IVUICS.	111	AUUUI	IIIIII ai	ıs via	minauv	CIAUVC.

- [3] Cardiac is Adult and Pediatric via Intraoperative;
- [5] Intraoperative includes abdominal, thoracic, and vascular.
- [\*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.

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